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UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

FILED
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2004 SEP 27 A 11:00
U.S. DISTRICT COURT
DISTRICT OF MASS.

UNITED STATES OF AMERICA ex rel. MICHAEL MAKALUSKY,

Plaintiff,

v.

SEALED

CEPHALON, INC.,

Defendant.

CIVIL ACTION NO: 05CV11904

COMPLAINT AND DEMAND FOR JURY TRIAL

FILED UNDER SEAL PURSUANT TO 31 U.S.C. § MAGISTRATE JUDGE Bowler

04-12066 RCL

INTRODUCTION

1. This is a *qui tam* action brought against the defendant pursuant to the False Claims Act, 31 U.S.C. §§ 3729, *et seq.* ("FCA"), seeking civil penalties, damages, declaratory relief, injunctive relief and such other relief as is available under the FCA, and demanding a trial by jury for all claims for which the right to a jury trial is authorized. This case arises from the defendant's unlawful participation in the presentment to the federal government of false or fraudulent claims for payment relating to the cancer drug Actiq (oral transmucosal fentanyl citrate).

JURISDICTION AND VENUE

2. This Court has jurisdiction under 28 U.S.C. § 1331, 28 U.S.C. § 1345, 31 U.S.C. § 3730 and 31 U.S.C. § 3732. Venue is proper in this district pursuant to 31 U.S.C. § 3732(a).

PARTIES

Plaintiff Michael Makalusky ("Relator") is an individual residing

I hereby certify on 9/27/05 that the foregoing document is a true and correct copy of the
☐ electronic docket in the captioned case
☐ electronically filed original filed on
☑ original filed in my office on 9/27/04
Fishers, Indiana
Sarah A. Thornton
Clerk, U.S. District Court
District of Massachusetts
By: Deputy Clerk

DOCKETED

4. Defendant Cephalon, Inc. ("Defendant") is a publicly-traded Delaware corporation with its corporate headquarters located at 145 Brandywine Parkway, West Chester, Pennsylvania. Defendant conducts business in all fifty states, including Massachusetts.

FACTUAL ALLEGATIONS

A. Overview

5. Defendant describes itself as "one of the world's fastest-growing biopharmaceutical companies[, which is] driven by [its] mission to deliver industry-leading growth by achieving the most efficient and sustainable means of delivering new value to the marketplace."

6. According to Defendant, it "specializes in drugs to treat and manage neurological diseases, sleep disorders, cancer and pain."

7. Defendant manufactures and markets the cancer drug Actiq.

8. Defendant acquired the rights to the cancer drug Actiq following its merger with Anesta Corporation ("Anesta") in or about October 2000.

9. In or about February 2001, Defendant's marketing and sales team "re-launched" Actiq.

10. Since that time, the increases in sales and the number of prescriptions of Actiq have been extraordinary. In fact, Defendant's total sales of Actiq between 2001 and 2003 increased by over 363%. The cancer drug Actiq ranked on NDCHealth's list of the Top 200 Drugs for 2003 by U.S. Sales.

11. Actiq sales in 2001 were more than $51 million, and 2002 sales increased to nearly $127 million - - a 146% jump in sales in the United States alone with an

increase of 152% in prescriptions written for Actiq in the United States. In 2003, sales rose to over $237 million and there was a 76% increase in prescriptions written in the United States. As for the first three months of 2004, Defendant realized over $70 million in sales from Actiq and increased prescriptions by another 60%. Defendant projects total 2004 sales of Actiq to fall somewhere between $325 and $375 million.

12. There has been a proportional increase in Medicaid reimbursement payments for Actiq made by the federal government. Between 2000 and 2003, the federal government's Medicaid reimbursements for Actiq skyrocketed by over thirteen hundred and fifty percent (1,350%). For each such year, the total Medicaid reimbursement payments for Actiq were as follows: $2,266,442 in 2000; $9,873,483 in 2001; $21,461,246 in 2002; and $33,050,099 in 2003. As for the first quarter of 2004, the federal government paid $11,006,480 for Actiq Medicaid reimbursements.

13. Defendant's promotion of Actiq for "off-label" uses have caused numerous false or fraudulent claims for payment under Medicaid to be submitted to the federal government over a long period of time in violation of 31 U.S.C. § 3729(a)(1), and Defendant's active assistance to physicians in securing Medicaid reimbursements for Actiq prescriptions that were ineligible for payment under Medicaid constitute separate violations of 31 U.S.C. § 3729(a)(2) and/or (a)(3). Further, Defendant's illegal kickbacks to physicians caused numerous false or fraudulent claims for payment under Medicaid to be submitted to the federal government in violation of FCA.

B. Actiq

14. Actiq (oral transmucosal fentanyl citrate) is a powerful, fast-acting, Schedule II narcotic painkiller. The analgesic potency of the opioid fentanyl citrate is

approximately eighty (80) to one hundred (100) times that of morphine, and, with Actiq, pain relief can begin within fifteen (15) minutes. After just twenty (20) to forty (40) minutes, the fentanyl in Actiq reaches the patient's brain, heart, lungs, kidneys, spleen and other tissues.

15. Given the strength of this cancer drug, any dose of Actiq to someone who does not already objectively manifest a tolerance to opioids (*e.g.*, persons taking at least sixty (60) mg of morphine per day) presents a significant danger of life-threatening hypoventilation or respiratory depression. The risk of death to children is particularly acute.

16. The fentanyl citrate in Actiq is artificially sweetened and given a raspberry flavor, and it is manufactured into a solid form which is attached to a stick. In essence, Actiq comes in the form of a lollipop. The medicine in Actiq is quickly absorbed through the mucous membrane on the inside of the patient's mouth while the patient sucks on the drug and twirls it between his or her cheek and gum.

17. On November 11, 1996, Anesta submitted to the Food and Drug Administration ("FDA") a new drug application ("NDA") for Actiq pursuant to the Federal Food, Drug and Cosmetic Act, 21 U.S.C. §§ 330, *et seq.* ("FDCA").

18. FDA initially found Anesta's NDA for Actiq to be inadequate, citing issues concerning safety, clinical efficacy and chemistry.

19. For instance, FDA was concerned, *inter alia*, with the fact that "[t]he risks of unintended overdose in opiate-tolerant and opiate-naïve patients or accidental ingestion associated with this product if used at home are significant." FDA Letter to Anesta, dated November 13, 1997.

20. On November 4, 1998, after ensuring that Actiq was reasonably safe and effective when used for its intended purpose, FDA approved the NDA for Actiq.

21. Pursuant to Subpart H of the NDA review regulations, *see* 21 CFR 314.520, however, FDA imposed significant restrictions on the distribution and use of Actiq.

22. According to the Actiq Product Label, Actiq is strictly limited to the following medical conditions of use:

> *Actiq* is indicated only for the management of breakthrough cancer pain in patients with malignancies who are **already receiving and who are tolerant to opioid therapy for their underlying persistent cancer pain**. Patients considered opioid tolerant are those who are taking at least 60 mg morphine/day, 50 μg transdermal fentanyl/hour, or an equianalgesic dose of another opioid for a week or longer.
>
> Because life-threatening hypoventilation could occur at any dose in patients not taking chronic opiates, *Actiq* is contraindicated in the management of acute or postoperative pain. This product **must not** be used in opioid non-tolerant patients.
>
> *Actiq* is intended to be used only in the care of cancer patients only by oncologists and pain specialists who are knowledgeable of and skilled in the use of Schedule II opioids to treat cancer pain.

23. "Breakthrough cancer pain [is] defined as a transient flare of moderate-to-severe pain occurring in cancer patients experiencing persistent cancer pain otherwise controlled with maintenance doses of opioid medications. . . ." Actiq Product Label.

24. The Actiq Product Label warns of the following contraindications:

> Because life-threatening hypoventilation could occur at any dose in patients not taking chronic opiates, *Actiq* is contraindicated in the management of acute or postoperative pain. . . . This product **must not** be used in opioid non-tolerant patients. Patients considered opioid tolerant are those who are taking at least 60 mg morphine/day, 50 μg transdermal fentanyl/hour, or an equianalgesic dose of another opioid for a week or longer.

Actiq is contraindicated in patients with known intolerance or hypersensitivity to any of its components or the drug fentanyl.

25. According to the Actiq Product Label, the Dose Titration for Actiq is as follows:

> The *initial dose of Actiq to treat episodes of breakthrough cancer pain should be 200 µg*. Patients should be prescribed an initial titration supply of six 200-µg *Actiq* units, thus limiting the number of units in the home during titration. Patients should use up all units before increasing to a higher dose.

26. FDA stressed the narrow indication of use for Actiq, warning Anesta "that this product has been approved **ONLY** for the management of breakthrough cancer pain in patients with malignancies who are already receiving and who are tolerant to opioid therapy for their persistent cancer pain. As such, please note that promotional statements or representations by you that this product may indeed be safe and efficacious in the treatment of diseases or patient populations beyond that contained in your approved labeling may be considered a violation of the [Federal Food, Drug and Cosmetic] Act." FDA Approval Letter for NDA 20-747, dated November 4, 1998, pg. 5 (emphasis in original).

27. During 2001 and 2002, several supplemental drug applications for Actiq were submitted by Anesta and/or Defendant, but none sought to expand the indicated use of the cancer drug Actiq. *See* NDA 20-747/S6; NDA 20-747/S8; NDA 20-747/S9; NDA 20-747/S10; NDA 20-747/S11.

28. The patents relating to the manufacture of Actiq are set to expire in May 2005 and September 2006.

29. To date, FDA has not approved the use of Actiq for any purpose other than for the treatment of breakthrough cancer pain in opioid-tolerant cancer patients.

C. Defendant's Off-label Promotion Of Actiq

30. Manufacturers, such as Defendant, are prohibited by federal law from marketing or promoting a drug for uses not approved by FDA, which uses are referred to as being "off-label." *See* 21 U.S.C. § 331.

31. Nevertheless, Defendant developed a strategy for Actiq to achieve extraordinary growth in product sales by aggressively promoting off-label uses for Actiq in violation of federal law.

32. Off-label uses for the cancer drug Actiq promoted by Defendant include treatment of the following: migraine pain; back pain; fibromyalgia; primary dysmenorrheal; post-operative pain; and pain associated with certain neurological disorders.

33. For purposes of carrying out its unlawful scheme, which ultimately caused false or fraudulent claims for payment under Medicaid to be submitted to the federal government in violation of FCA, Defendant:

a. trained its Actiq sales representatives, who Defendant referred to as "Pain Care Specialists," to promote various off-label uses for Actiq in sales pitches or "details" to physicians;

b. instructed its Actiq sales representatives to use promotional materials for Actiq that had not been approved by FDA for use in marketing when making "details" to physicians, and ordered its Actiq sales representatives to not leave such unapproved promotional materials with physicians in order to deter detection of Defendant's unlawful scheme;

c. instructed its Actiq sales representatives to target any physician who was writing a large number of prescriptions for narcotics generally, regardless of the physician's specialty;

d. ordered its Actiq sales representatives not to target oncologists, because such physicians account for a very small percentage of the total number of prescriptions written in the narcotics market;

e. organized and financed Medical Education Programs, Continuing Medical Education seminars and other "educational opportunities" during which presentations were made concerning off-label uses for Actiq;

f. organized and financed "consultants" meetings during which presentations were made promoting off-label uses for Actiq;

g. used "Medical Liasons" to promote off-label uses for Actiq;

h. avoided the creation of documents and references in documents otherwise created in Defendant's ordinary course of business regarding the promotion of Actiq that would constitute a violation of FDCA and/or FCA in order to deter detection of Defendant's unlawful scheme; and

i. actively assisted physicians in securing Medicaid reimbursements for Actiq prescriptions that were ineligible for payment under Medicaid in order to ensure that these physicians continued to prescribe Actiq.

Training

34. Defendant's core message to its Actiq sales representatives, who were referred to by Defendant as "Pain Care Specialists," was that "pain is pain." That is, notwithstanding the fact that FDA approved Actiq solely for the treatment of

"breakthrough cancer pain in patients with malignancies who were already receiving and who are tolerant to opioid therapy for their underlying persistent cancer pain", Defendant trained its Actiq sales representatives to promote Actiq for the treatment of breakthrough pain in general.

35. In or about December 2002, when Relator was interviewed by Defendant for an Actiq sales representative position, Ms. Stacey Miller ("Miller"), Defendant's Area Manager for Actiq for the Southeast Region, and Mr. Bill Carohan ("Carohan"), Miller's supervisor, explained to Relator that the majority of physicians who prescribe Actiq are not oncologists and that physicians use the drug "for breakthrough pain in general." Miller stated that "most physicians agree that pain is pain regardless of whether it is caused by cancer or other sources."

36. On or about February 22, 2003, Defendant held a six-day conference in Las Vegas, Nevada. Near the conclusion of this national conference, Defendant's Chairman and Chief Executive Officer, Dr. Frank Baldino, Jr. ("Baldino"), informed all of Defendant's sales representatives that FDA personnel had been present at the conference and had attempted to speak with certain of Defendant's employees. Following Baldino's address, Miller instructed all Actiq sales representatives in the Southeast Region, including Relator, Mr. Ray Lanza, Mr. Dan Tondre, Mr. R. Todd Guttery, Mr. James Pontello, Mr. Matthew Reynolds and Ms. Holly Sherrer, to be careful about what they wrote in their sales Call Notes concerning the promotion of Actiq for off-label uses because "those notes could be subpoenaed."

37. On or about March 10-14, 2003, Defendant held an intensive Actiq training program in Philadelphia, Pennsylvania for Actiq sales representatives ("the

March 2003 Training") during which the Actiq sales representatives were taught to use the "pain is pain" sales pitch in promoting Actiq. Ms. Loren Mangus, Defendant's Manager of Sales Training and Development, was the person primarily responsible for conducting the March 2003 Training. Defendant's Area Managers for Actiq from around the country made presentations to the Actiq sales representatives as part of the March 2003 Training.

38. As part of the March 2003 Training, one of Defendant's Area Managers for Actiq made a PowerPoint presentation to the Actiq sales representatives during which he told the Actiq sales representatives that Defendant's goal for Actiq was "to grow our use in the narcotics market." The Area Manager instructed the Actiq sales representatives to target physicians who write a large number of prescriptions for narcotics, regardless of specialty. The Actiq sales representatives were shown a chart displaying percentages of narcotics prescriptions written by physician specialty, with anesthesiologists and neurologists at the top of the chart and oncologists near the bottom. Based on this data, the Area Manager specifically instructed the Actiq sales representatives not to target oncologists, since such doctors account for a very small percentage of the narcotics market.

39. As part of the March 2003 Training, the Actiq sales representatives were further trained by Defendant's Area Mangers for Actiq to target physicians, regardless of specialty, who were writing a large number of prescriptions for the drug Duragesic. The Actiq sales representatives were told that such physicians could more easily be convinced to switch from prescribing Duragesic to prescribing Actiq, since both drugs contain fentanyl.

40. In conformance with the teachings of the March 2003 Training, Relator's supervisor, Miller, specifically instructed Relator to generate computerized reports that would identify the top fifty (50) physicians in his territory according to the number of prescriptions written for short-acting opioids, long-acting-opioids and Duragesic. Miller told Relator, "those are your targets."

41. On or about June 4-5, 2003, Defendant held a Regional Meeting in Baltimore, Maryland for Actiq sales representatives ("the June 2003 Training"). As part of the June 2003 Training, the "pain is pain" sales pitch for promoting Actiq was reiterated to Actiq sales representatives.

42. As part of the June 2003 Training, all Actiq sales representatives were specifically instructed that promotional materials for Actiq that had not been approved by FDA for use in marketing, but which were nevertheless used in making "details" to physicians, should not be left with physicians. Defendant's Actiq sales representatives were further reminded to be cautious about writing incriminating details in their sales Call Notes concerning the promotion of Actiq for off-label uses.

43. Defendant's training of its Actiq sales representatives also included mandatory "field rides" with Area Trainers. For example, Relator was paired with Mr. Ray Lanza ("Lanza"), Defendant's Area Trainer for the Southeast Region, to go on such "field rides" on or about March 17-21, 2003 ("the March 2003 Field Rides").

44. During the March 2003 Field Rides, Lanza promoted Actiq off-label to more than six (6) physicians, including Dr. Bart Gatz and Dr. Sheryl Lavender.

45. During the March 2003 Field Rides, Lanza told Relator that it was Lanza's responsibility to ensure that Relator conveyed the messages about Actiq's "various uses"

in making "details" to physicians. Lanza instructed Relator to discuss breakthrough pain in general (*i.e.*, not limited to breakthrough cancer pain) with physicians, and told Relator to compare Actiq to whatever narcotic the particular physician was prescribing in order to convince the physician to switch to Actiq.

46. During the March 2003 Field Rides, Lanza explicitly coached Relator to employ the following pat "pain is pain" response to questions concerning Actiq's narrow label: "Yes, we are indicated for cancer pain, but wouldn't you agree that pain is pain."

47. During the March 2003 Field Rides, Lanza provided Relator with a conversion chart for Actiq that showed supposedly equivalent doses of other narcotics, such as Percocet and Vicodin. For instance, according to the Actiq conversion chart, one 200mcg dose of Actiq was said to be roughly equivalent to "2 to 3 Percocet." Lanza explicitly trained Relator to use the Actiq conversion chart to convince physicians that it was easy to switch from other pain medications to Actiq for use in non-cancer breakthrough pain.

48. During the March 2003 Field Rides, Lanza also taught Relator that the Actiq conversion chart should be used to show physicians how to prevent "a failure," which was defined as a situation where a patient complained that the prescribed dose of Actiq was ineffective. This promotion strategy was inextricably tied to Defendant's internal objective of convincing physicians "to start with 400mcg and to titrate aggressively." As Lanza explained to Relator, by telling doctors that 200mcg of Actiq was the equivalent to just "2 to 3 Percocet," he could convince doctors to begin a patient at the 400mcg dose of Actiq and to titrate aggressively in order to prevent patients from complaining that Actiq was not providing adequate pain relief.

49. The Actiq conversion chart had not been approved by FDA for use in marketing, and Lanza told Relator to never leave the Actiq conversion chart at a physician's office.

50. Defendant further trained its Actiq sales representatives to employ off-label clinical studies in promoting Actiq to physicians, notwithstanding the fact that such promotional materials had not been approved by FDA for marketing purposes.

51. For example, as part of the March 2003 Field Rides, Lanza provided Relator with a clinical trial study concerning the use of Actiq for the treatment of migraine pain, which promotional material had not been approved by FDA for use in marketing. Nevertheless, Lanza specifically instructed Relator to use the migraine clinical study in promoting Actiq to physicians, particularly neurologists. Lanza emphasized to Relator that the migraine clinical study should not be left at a physician's office, and Lanza instructed Relator that, if a physician asked to keep the clinical study, the standard response was to say that a request would be made to have the clinical study mailed to the physician.

52. Another clinical study not approved by FDA for use in marketing, but commonly used by Actiq sales representatives in making "details" to physicians, was the so-called "double barrel study." In general terms, this clinical study reported that using two units of a 400mcg dose of Actiq at once had the same analgesic effect as using one unit of a 800mcg dose of Actiq. The "double barrel study" was used by Actiq sales representatives as part of the standard sales pitch that physicians should begin a patient at 400mcg of Actiq and should titrate aggressively.

53. As part of Defendant's training and supervision of its Actiq sales representatives, Area Managers for Actiq were obliged to occasionally accompany each Actiq sales representative under their supervision on "details" to physicians' offices. Defendant's Area Managers for Actiq reported their observations and evaluations from such supervised "field rides" in Field Contact Reports.

54. For example, Miller, Relator's supervisor, accompanied Relator on "field rides" and supervised Relator's "details" to physicians on at least the following dates: April 15-16, 2003; May 28-29, 2003; June 12, 2003; August 13, 2003; and September 24, 2003. On each of these dates, Realtor promoted Actiq off-label in the presence of Miller, and often with her assistance. Physicians to whom Actiq was promoted off-label included, but were not limited to, the following: Dr. Todd Jaffe; Dr. Bart Gatz; Dr. Anthony Afong; and Dr. Daniel Ettedgui.

Speakers

55. A critical aspect of Defendant's off-label promotion of Actiq is the use of Medical Education Programs ("MEP"), Continuing Medical Education ("CME") seminars and other "educational opportunities." Indeed, Defendant allotted each of its Actiq sales representatives a substantial budget with which to develop speakers for Actiq's promotion.

56. In arranging such "educational opportunities," Relator and Defendant's other Actiq sales representatives were responsible for selecting the presenter(s) and for specifying the topics to be discussed. Both the suggested speakers and topics had to be approved by an Area Manager for Actiq. Physicians who wrote a large number of prescriptions for Actiq or other short-acting opioids would be targeted by Relator and

Defendant's Actiq sales representatives to make presentations on behalf of Defendant. Defendant paid such physicians an "honorarium" in the range of five hundred dollars ($500.00) to two thousand dollars ($2,000.00) per presentation.

57. Miller told Relator that Dr. Steven Shoemaker ("Shoemaker") should be used as a presenter. Shoemaker was a frequent presenter on behalf of Defendant who was particularly effective in promoting off-label uses of Actiq, as he was a former Anesta employee who claimed to have assisted in submitting the NDA for Actiq to FDA. During his presentations, Shoemaker frequently used the line, "If Actiq works on cancer pain, imagine what it can do for [back/migraine, etc.] pain."

58. Miller also specifically instructed Relator that it would be a "good idea" for Relator to schedule a speaker to discuss the use of Actiq for the treatment of migraine pain to Dr. Lisa Banchik, a neurologist.

59. Further, Miller forwarded a voicemail message to all Actiq sales representatives in the Southeast Region that had been sent by Mr. Matt Reynolds ("Reynolds"), a Pain Care Specialist from the Orlando, Florida territory. In the voicemail message, Reynolds stated that he had effectively used Dr. Scharfman, a neurologist, as a speaker to promote Actiq for the treatment of migraine pain and that Reynolds could assist in arranging similar presentations.

60. Among the presentations that were arranged by Relator and approved by his supervisor, Miller, which involved the promotion of off-label uses for Actiq were the following:

a. On or about April 25, 2003, Shoemaker gave a presentation at the office of Dr. Dana Richard, a family practitioner. Among the topics discussed by

Shoemaker was the use of Actiq for the treatment of non-cancer breakthrough pain, including back pain and migraine pain;

b. On or about May 15, 2003, Shoemaker gave a presentation at the office of Dr. Jose Torres, a family practitioner. Among the topics discussed by Shoemaker was Actiq's equivalency to other narcotics (*e.g.*, 200mcg Actiq is roughly equivalent to 2-3 Percocet);

c. On or about May 15, 2003, Shoemaker gave a presentation to Dr. Bart Gatz. Among the topics discussed by Shoemaker was non-cancer breakthrough pain in the context of Shoemaker's explanation that Actiq's label was restricted to cancer pain only because "one lady on the FDA board was concerned with children";

d. On or about June 11, 2003, Dr. Harold Cordner ("Cordner") gave a presentation to Dr. Burman and Dr. Luck at the New York Prime Steakhouse restaurant in Boca Raton, Florida. Among the topics discussed by Cordner were the use of Actiq for the treatment of back pain resulting from failed back surgeries, and beginning patients on 400mcg of Actiq and titrating aggressively. Defendant paid Cordner approximately seven hundred and fifty dollars ($750.00) to give this presentation on Actiq;

e. On or about June 14, 2003, Shoemaker and Dr. Miguel gave a presentation at the Governor's Club in West Palm Beach, Florida. Among the topics discussed was the use of Actiq for the treatment of migraine pain; and

f. On or about August 7, 2003, Dr. Tailor gave a presentation at Joseph's restaurant in Stewart, Florida. Among the topics discussed was the use of Actiq for the treatment of fibromyalgia, back pain and migraine pain.

"Medical Liasons"

61. Defendant also employed so-called "Medical Liaisons" to assist in promoting Actiq for off-label uses.

62. Both Miller and Lanza instructed Relator that he should use Ms. Bonnie Lewis ("Lewis"), one of Defendant's "Medical Liaisons", to assist in promoting Actiq. Relator was told that Lewis' status as a nurse would be extremely helpful in overcoming physicians' objections to prescribing Actiq. Relator was further told that if Lewis was unable to convince the particular physician to prescribe Actiq, Relator should arrange for Shoemaker, Lewis' fiancé at the time, to give a presentation.

"Consultants"

63. Defendant also held so-called "consultants meetings" as a means of inducing physicians to prescribe Actiq and/or recommend other physicians to prescribe Actiq. Defendant paid the travel and lodging expenses of physicians who were invited by Defendant to attend such "consultants meetings."

64. For example, Defendant held a "National Consultants Meeting" in San Diego, California on or about May 3-4, 2003.

65. Relator was told by his supervisor to "invite" two physicians from within his territory to attend the "National Consultants Meeting" at Defendant's expense. After discussing the matter with Miller, Relator recommended Dr. Lily Voepel and Dr. Lisa Banchik as his "invitees" to the conference. Although Dr. Voepel was an orthopedist, and Dr. Banchik a neurologist, they were selected to attend the Actiq conference because they wrote a large number of prescriptions for narcotics, but a small number of prescriptions for Actiq. As Miller explained to Relator, "there was potential for growth"

with these particular physicians. Miller granted approval to Relator's recommendations, and Drs. Voepel and Banchik attended the "National Consultants Meeting" in San Diego.

66. At some point after the "National Consultants Meeting", Relator visited Dr. Banchik's office for promotional purposes. Dr. Banchik told Relator that "everything went great in San Diego," or words to that effect, and she assured Relator that she would "try to use Actiq more." In fact, Dr. Banchik introduced Relator to a patient who was experiencing pain from a failed back surgery, and Dr. Banchik reported that she had prescribed the patient 800mcg of Actiq. Relator reported this to Miller, to which Miller said something to the effect, "Good. Hopefully, she'll write more."

Contest

67. As another method of increasing the market share of Actiq within the narcotics market, Defendant held the "2003 Actiq Contest." On or about March 31, 2003, Nancy Shanfelt, a Sales Information Analyst for Defendant, sent an electronic mail message to all Area Managers for Actiq and all Actiq sales representatives explaining the contest.

68. According to its guidelines, the contest was "based on a measure of the number of new Actiq writers who reach the following levels: (1) a minimum level of 6 TRx per quarter and average 24 Units/Rx; and (2) a minimum level of 12 TRx per quarter and average 48 Units/RX." Moreover, "[p]rescribers already at the first level [were] excluded from that level for all future quarters; prescribers already at the second level [were] excluded from both levels for all future quarters."

69. Attached to the Shanfelt electronic mail were Excel spreadsheets identifying physicians (by name, address and specialty) and listing the number of Actiq

prescriptions written by each such physician for certain past quarters. Physicians listed on the spreadsheets were "disqualified" from levels of the contest, not because of their specialty, but because they had already reached the specified prescription targets. Conversely, physicians identified in the spreadsheets provided to the Actiq sales representatives who had not reached the specified prescription targets qualified for the "2003 Actiq Contest" regardless of whether such physicians were "oncologists [or] pain specialists who [were] knowledgeable of and skilled in the use of Schedule II opioids to treat cancer pain." Actiq Product Label.

Medicaid Reimbursement

70. Defendant made it a priority to actively assist doctors in securing Medicaid reimbursement for Actiq in order to ensure that such physicians continued to prescribe Actiq. For example, Defendant trained its Actiq sales representatives about Medicaid and its product formulary, and expected its Actiq sales representatives to "gather intelligence" on the providers in their sales territory who were Pharmacy & Therapeutics Committee Members for the state Medicaid plan and managed care plans.

71. Further, on its Internet web-site, http://www.cephalon.com, Defendant advertises its "Actiq Reimbursement Program", and advises physicians that "Actiq is eligible for Medicaid reimbursement in all 50 states; however, coverage may vary from state to state." Defendant, therefore, provides a 1-800 number so physicians can "reach highly trained reimbursement specialists with expertise in payer relations and in resolving reimbursement issues."

72. Many physicians expressed their concerns to Defendant's Actiq sales representatives about getting Medicaid reimbursements for Actiq prescriptions. For

example, in Miller's Field Contact Report of one of Relator's details to Dr. Todd Jaffe's office on or about April 15 or 16, 2003, Miller wrote:

> Marsha is Dr. Jaffe's MA. She is responsible for pushing the prior authorizations through Medicaid and other insurance plans. While we were in the office, we learned she was having difficulty obtaining authorization for a Medicaid patient. This is just another reason to conduct 'complete calls' in every office so that you are aware of any problems occurring with Actiq.

73. At some point during his tenure with Defendant, Relator received a complaint from a doctor's office about getting a claim for reimbursement for Actiq approved by Medicaid. Relator took the complaint to his supervisor, Miller, who directed Relator to contact Mr. Dan Tondre ("Tondre"), a Senior Actiq Pain Care Specialist, for instructions on dealing with the issue.

74. Miller also sent a voicemail message to all Actiq sales representatives in the Southeast Region in which Miller specifically instructed these Actiq sales representatives to contact Tondre if any doctor reported having a problem getting Actiq approved by Medicaid.

75. Tondre told Relator to instruct the doctor's office that was having difficulty in getting Actiq approved for reimbursement to falsely tell the Medicaid representative that the patient in question had previously failed on two, different narcotics and, as a last resort, Actiq was prescribed.

76. According to Tondre, he had personally instructed doctors' offices to change the medical records of patients to falsely indicate that the patients had been prescribed Actiq because they had previously failed on two, different narcotics.

77. Tondre also told Relator that he (Tondre) had personally made telephone calls on behalf of doctors in order to obtain reimbursement for Actiq prescriptions.

Tondre, who also happened to be a nurse, explained that, if he was at a doctor's office that was having a problem with obtaining reimbursement, he would call and introduce himself as "nurse Tondre calling from Dr. ___'s office," which made it easier for him to obtain reimbursement.

78. Miller, as the Area Manager, required this procedure for assisting doctors with reimbursement issues to be followed, with the caveat that the Actiq sales representatives should be "careful" about contacting Medicaid directly.

79. As ordered by his superiors, Relator delivered Defendant's Medicaid reimbursement message to the following doctors' offices: Dr. Anthony Rogers; Dr. Dana Richard; Dr. David Glener; Dr. Anthony Afong; Dr. Robert Lentz; Dr. Jose Torres; Dr. Lily Voepel; Dr. Howell Goldfarb; Dr. Bart Gatz; Dr. Todd Jaffe; Dr. Harold Cordner; Dr. Charles Rattray; Dr. Wayne Weidenbaum; Dr. Sheryl Lavender; Dr. William Berman; Dr. Jonathan Greer; Dr. Hal Tobias; Dr. Howard Busch; Dr. Ramon Alvarez; Dr. Stanley Golovac; Dr. Keith Dietrick; and Dr. Richard Gayles.

COUNT I – VIOLATIONS OF THE FALSE CLAIMS ACT

80. Relator realleges and incorporates the preceding paragraphs as if fully set forth herein.

81. Relator has direct and independent knowledge of the information on which the allegations are based, and has voluntarily disclosed to the federal government substantially all material evidence and information possessed by Relator prior to filing this *qui tam* action.

82. Defendant's actions as detailed above resulted in numerous violations of FCA occurring over a long period of time. Further evidence of Defendant's violations of FCA resides within Defendant's exclusive possession and/or control.

83. In violation of 31 U.S.C. § 3729(a)(1), Defendant knowingly caused to be presented to the federal government numerous false or fraudulent claims for payment or approval of Medicaid reimbursements for Actiq prescriptions.

84. Generally speaking, the federal government will reimburse States for "covered outpatient drugs" under Medicaid. *See* 42 U.S.C. §§1396r-8(a)(1), 1396b. "The term 'covered outpatient drug' does not include . . . a drug . . . used for a medical indication which is not a medically accepted indication." 42 U.S.C. § 1396r-8(k)(3). "A State may exclude or otherwise restrict coverage of a covered outpatient drug if . . . the prescribed use is not for a medically accepted indication (as defined by subsection (k)(6))[.]" 42 U.S.C. § 1396r-8(d)(1)(B)(i).

85. "The term 'medically accepted indication' means any use . . . which is approved under the Federal Food, Drug, and Cosmetic Act or the use of which is supported by one or more citations included or approved for inclusion in any of the compendia described in subsection (g)(1)(B(i)." 42 U.S.C. § 1396r-8(k)(6). The referenced compendia are (i) American Hospital Formulary Service Drug Information, (ii) United States Pharmacopeia-Drug Information and (iii) DRUGDEX Information System. 42 U.S.C. § 1396r-8(g)(1)(B)(i).

86. The only medically accepted indication, as that term is defined at 42 U.S.C. § 1396r-8(k)(6), for Actiq is the treatment of breakthrough cancer pain in opioid-tolerant cancer patients.

87. Defendant's promotion as described above of Actiq for the use in the treatment of non-cancer breakthrough pain knowingly caused numerous Medicaid claims to be submitted in states that do not permit Medicaid reimbursement for off-label, non-compendium drug prescriptions. All such claims are false or fraudulent in violation of 31 U.S.C. § 3729(a)(1).

88. As a separate and independent basis of liability under FCA, Defendant committed numerous violations of 31 U.S.C. § 3729(a)(2) by making, using and/or causing to be made or used false records or statements to get false or fraudulent claims for Medicaid reimbursements for Actiq prescriptions to be paid or approved by the federal government. As detailed above, Defendant advised physicians that Medicaid reimbursement for Actiq prescriptions could be obtained by falsely asserting that the patient had previously failed on two, different narcotics and, as a last resort, Actiq was prescribed.

89. As a separate and independent basis of liability under FCA, Defendant committed numerous violations of 31 U.S.C. § 3729(a)(3), by conspiring to defraud the federal government by getting false or fraudulent claims for Medicaid reimbursements for Actiq prescriptions paid. Defendant conspired with various physicians to obtain Medicaid reimbursement for Actiq prescriptions by, *inter alia*, falsely asserting to Medicaid that patients had previously failed on two, different narcotics and, as a last resort, Actiq was prescribed.

COUNT II – MEDICAID ANTI-KICKBACK VIOLATIONS

90. Plaintiff realleges and incorporates herein paragraphs 1 through 73 above.

91. According to the Medicaid Anti-Kickback statute, it is illegal to knowingly and willingly offer or pay any remuneration directly or indirectly, overtly or covertly in cash or in kind to any person to induce such person to, *inter alia*, purchase or order, or recommend for purchasing or ordering, a good covered in whole or in part under a Federal health care program. 42 U.S.C. § 1320a-7b(b)(2).

92. According to the Medicaid Anti-Kickback statute, it is illegal to knowingly and willingly solicit or receive any remuneration directly or indirectly, overtly or covertly in cash or in kind in return for, *inter alia*, purchasing or ordering, or recommending purchasing or ordering, a good covered in whole or in part under a Federal health care program. 42 U.S.C. § 1320a-7b(b)(1).

93. Medicaid claimants expressly and/or impliedly certify that their claims for reimbursement have not been tainted by such illegal kickbacks.

94. A false express and/or implied certification that claims for Medicaid reimbursement are not tainted by such illegal kickbacks constitutes a false or fraudulent claim under FCA.

95. Defendant's actions as detailed above, including its payments to physicians to make presentations and/or attend "consultants meetings", constituted illegal kickbacks.

96. By paying such illegal kickbacks to physicians, Defendant knowingly caused to be presented to the federal government numerous false or fraudulent claims for

payment or approval of Medicaid reimbursements for Actiq prescriptions in violation of FCA.

COUNT III – INJUNCTIVE AND DECLARATORY RELIEF

97. Relator realleges and incorporates the preceding paragraphs as if fully set forth herein.

98. There exists an actual controversy between the federal government and Defendant.

99. Relator, on behalf of the federal government, requests the following equitable relief:

a. that a judicial determination and declaration be made of the rights of the federal government and the corresponding responsibilities of Defendant;

b. that Defendant be ordered to cease its unlawful practice of promoting off-label uses for Actiq and providing assistance in securing Medicaid reimbursements for Actiq that are ineligible for payment; and

c. that any further equitable relief that this Court deems just be afforded the federal government.

PRAYER FOR RELIEF

WHEREFORE, Relator prays for judgment against Defendant and for relief as follows:

1. for civil penalties as allowed under 31 U.S.C. § 3729;
2. for damages as allowed under 31 U.S.C. § 3729;
3. for declaratory and injunctive relief;
4. for expenses, attorneys' fees and costs pursuant to 31 U.S.C. § 3730;
7. for interest; and
8. for such other and further relief as this Court deems just.

JURY DEMAND

RELATOR DEMANDS A JURY TRIAL ON ALL ISSUES SO TRIABLE.

Respectfully submitted,
For the Relator,

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Dated: September 27, 2004